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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,038	07/17/2002	Harald Bruessow	112843-042	9705
29157	7590	01/13/2006	EXAMINER	
BELL, BOYD & LLOYD LLC P. O. BOX 1135 CHICAGO, IL 60690-1135			CHOWDHURY, IQBAL HOSSAIN	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 01/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/070,038	<b>Applicant(s)</b> BRUESSOW ET AL.	
	<b>Examiner</b> Iqbal Chowdhury, Ph.D.	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10 and 18-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/26/02</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This application is a 371 of PCT/EP00/07696 filed on 7/17/2002.

The preliminary amendment filed on 7/17/2002 amending claims 2-6 and 8-10, and newly added claims 11-27 is acknowledged. Claims 1-27 are pending and are present for examination.

Applicant's election without traverse of Group I claims 1-7, 9-10, and 18-27 in the communication filed on 10/21/2005 is acknowledged. Claims 8 and 11-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-7, 9-10, and 18-27 are at issue and are present for examination.

### ***Claim Objections***

Claims 2-7 are objected to because of the recitation "A bacterium -----", which refers to a previous claim. "A bacterium -----" should be changed to "The bacterium -----". Appropriate correction is required.

Claims 18-20 are objected to because of the recitation "A composition -----", which refers to a previous claim. "A composition -----" should be changed to "The composition -----". Appropriate correction is required.

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Claims 22-24 are objected to because of the recitation “A starter culture -----“, which refers to a previous claim. “A starter culture -----“, should be changed to “The starter culture ---- --“. Appropriate correction is required.

Claims 24-27 are objected to because of the recitation “A milk product -----“, which refers to a previous claim. “A milk product -----“, should be changed to “The milk product ----- “. Appropriate correction is required.

Claim 1 is objected to because of the recitation “S thermophilus bacterium”. The “S thermophilus bacterium” should be changed to “Streptococcus thermophilus bacterium”.

Claims 9-10 and 21 are objected to because of the recitation “S-thermophilus bacterium”. The “S-thermophilus bacterium” should be changed to “S. thermophilus bacterium”.

Claims 1-7, 9-10, 18, 21, 22 and 25 are objected to because of the following informalities: Bacterial species names should be italicized or underlined. Appropriate correction is required.

Claim 5 is objected to because of the recitation following informalities: Bacterial species names should be italicized or underlined. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is indefinite in the recitation of the “functional equivalent

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thereof” which is ambiguous and confusing. What function does the sequence of ISS1 encompass? Does “functional equivalent” mean the same activities of wild type protein or does it mean something else.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is unclear the way it is written with the recitation “addition of DNA at least one site --- ORF 90 a site which disrupts expression of a chorismate mutase chain A gene, disrupts expression of the down stream gene ORF 394 and ORF 269 at site which disrupts expression of an oxidoreductase gene”. An appropriate correction is required.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is indefinite and unclear with the recitation “modification comprises a deletion of at least a part of ORF 1560”. What does “part of ORF 1560” means?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-7, 9-10 and 18-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a mutant of *S. thermophilus* bacterium due to the modification of bacterial chromosome, which is

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resistant to attack by bacteriophages due to the insertion of a DNA fragments into the bacterial chromosome or mutation in the prophage genome.

The specification does not contain any disclosure of the structure of all the modifications of a *S. thermophilus* bacterial chromosome or prophage coding region resulting in resistance to bacteriophage infection. The genus of mutant *S. thermophilus* bacterium, which is resistant to attack by bacteriophages, is a large variable genus with the potentiality of having mutations at many different sites of the chromosome, which disrupt the expression of many different proteins and thus have many different effects. The specification does not disclose adequate structure of the modifications of the *S. thermophilus* bacterial chromosome or prophage genome, which resulted in the generation of a mutant strain, which is resistant to attack by bacteriophage. The specification fails to describe sufficient information to put one of skill in the art in possession of the claimed invention. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

Claims 1-4, 6-7, 9-10 and 18-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a modified *S. thermophilus* having a modification of bacterial chromosome in ORF90 due to an insertional mutation which disrupts the expression of the chorismate mutase chain A gene or in ORF269 due to an insertional mutation resulting in disruption of expression of the encoded oxidoreductase gene or a deletion in the prophage genome of *sfi21* in ORF1560 which disrupts the expression of the prophage, and

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starter culture and milk products thereof, does not reasonably provide enablement for any modification of *S. thermophilus* bacterial chromosome or any modification of prophage *sfi21* genome, wherein *S. thermophilus* bacterial strain becomes resistant to attack by bacteriophage, and starter culture and milk products thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claim 1-4, 6-7, 9-10 and 18-27 are so broad as to encompass any mutant of *S. thermophilus* bacterium due to the modification of bacterial chromosome or prophage genome, resistant to attack by bacteriophage and starter culture and milk products thereof. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to any mutant of *S. thermophilus* bacterium due to any modification of bacterial chromosome (claims 1-4, 9-10, 18-19, 21-23 and 25-26) or any modification of *sfi21* prophage genome (claims 6, 20, 24 and 27) or any modification in the ORF1560 of prophage *sfi21* genome broadly encompassed by the claims. While methods of preparing a bacterial strain by mutating prophage genome and the bacterial chromosome in *S. thermophilus* bacterium in vitro are well known in the art, mutating bacterial chromosome or prophage genome in the bacterial stain so as to produce a strain resistant to any phage infection is not routine. Knowledge of two modifications of *S. thermophilus* bacterial chromosome or one modification in prophage genome, which is resistant to attack by a specific bacteriophage in the said bacterium are unlikely to be provide any guidance for producing other types of mutants of *S. thermophilus* bacterial species resistant to infection by bacteriophage. However, in this case the disclosure is limited to two mutants of *S. thermophilus* bacterial chromosome and one mutant of prophage genome.

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Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any modification of *S. thermophilus* bacterial chromosome resistant to attack by bacteriophage or any modification in the prophage genome. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, any mutant of *S. thermophilus* bacterium due to the modification of bacterial chromosome or prophage genome, having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 9-10, 19, 21, 23, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Sturino et al. ("Construction of bacteriophage resistant strains of *Streptococcus thermophilus* by pGh9::ISS1 insertional mutagenesis", *Journal of Dairy Science*, vol. 81, no. Suppl. 1, 1998, p. 7, Joint Meeting of the American Society for Animal Science; Denver, Colorado, USA; July 28-31, 1998, see IDS). Sturino et al teach the construction of bacteriophage resistant strains of *Streptococcus thermophilus* by pGh9::ISS1 mediated insertional mutagenesis



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and subsequent challenge by bacteriophage infection resulted in delayed or reduced propagation of the phage replication in the said bacterium. Sturino et al further teach the use of this resistant strain in the fermentation process in the milk industry as a starter culture.

Claims 1-2, and 6, 9 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Foley et al. ("A short noncoding viral DNA element showing characteristics of a replication origin confers bacteriophage resistance to *Streptococcus thermophilus*", Virology. 1998 Oct 25; 250(2): 377-87, see IDS). Foley et al teach *S. thermophilus* strains having deletion of a noncoding DNA fragment from the DNA replication module of phage phiSfi21, which resulted in a *Streptococcus thermophilus* strain Sfi1 resistant from infection by 17 of 25 phages.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 24-25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sturino et al. ("Construction of bacteriophage resistant strains of *Streptococcus thermophilus* by pGh9::ISS1 insertional mutagenesis", *Journal of Dairy Science*, vol. 81, no. Suppl. 1, 1998, p. 7, Joint Meeting of the American Society for Animal Science; Denver, Colorado, USA; July 28-31, 1998, see IDS) in view of Foley et al. ("A short noncoding viral DNA element showing characteristics of a replication origin confers bacteriophage resistance to *Streptococcus thermophilus*", *Virology*. 1998 Oct 25; 250(2): 377-87, see IDS). Sturino et al teach the construction of bacteriophage resistant strains of *Streptococcus thermophilus* by pGh9::ISS1 mediated insertional mutagenesis and subsequent challenge by bacteriophage infection resulted in delayed or reduced propagation of the phage replication in the said bacterium. Sturino et al further teach the use of this resistant strain in the fermentation process in the milk industry as a starter culture. Sturino et al. did not teach the deletion of noncoding viral DNA element confers Bacteriophage resistance to *S. thermophilus*. Foley et al teach deletion of a noncoding DNA fragment from the DNA replication module of phage phiSfi21 resulted *Streptococcus thermophilus* strain Sfi1 resistant from infection by 17 of 25

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phages including phiSfi21.

Therefore, it would have been obvious to one of ordinary skill in the art to use a *S. thermophilus* bacterium containing deleted phage genome or mutated bacterial chromosome, which is resistant to phage infection in the milk industry as a starter culture to produce milk product as taught by Sturino et al. and Foley et al.

### ***Conclusion***

#### **Status of the claims:**

Claims 1-7, 9-10 and 18-27 are pending.

Claims 1-7, 9-10 and 18-27 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Respectfully,

Iqbal Chowdhury, PhD

Patent Examiner

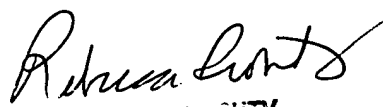
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